

PHARMACY BOARD[657]

Adopted and Filed Emergency

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The amendment relates to the responsibilities of the pharmacies when a pharmacy closes. Those responsibilities include notifications by the closing pharmacy to the Board and the federal Drug Enforcement Administration (DEA) at least 30 days prior to the pharmacy closing and the content of those notifications; notification to the pharmacist in charge of the closing pharmacy at least 40 days prior to the pharmacy closing and including the pharmacist in charge in the notification and closing processes; notification to patients of the closing pharmacy at least 30 days prior to the date of closing and addressing direct communication to patients and the posting of signs or other public notices; notification to the pharmacist in charge of the receiving pharmacy at least 30 days prior to the pharmacy closing; and requiring cancellation or revocation of all authorizations to utilize the DEA’s online controlled substances ordering system (CSOS) on behalf of the closing pharmacy. The amendment also requires that the closing pharmacy ensure the transfer of all patient records to a pharmacy that is held to the same standards of confidentiality as the closing pharmacy and that agrees to act as custodian for the closing pharmacy’s records for the retention periods required under federal and state laws, rules, and regulations.

Requests for waiver or variance of the discretionary provisions of this rule will be considered pursuant to 657—Chapter 34.

The amendment was adopted during the August 10, 2011, teleconference meeting of the Board of Pharmacy.

The Board finds, pursuant to Iowa Code section 17A.4(3), that notice and public participation are unnecessary and impracticable due to the immediate need for this amendment in order to ensure that the previously Adopted and Filed amendment to subrule 8.35(7) published as Item 4 in **ARC 9526B** in the June 1, 2011, Iowa Administrative Bulletin will not become effective. The Administrative Rules Review Committee, at its meeting on June 14, 2011, imposed a 70-day delay on the effective date of subrule 8.35(7) as published in Item 4 of **ARC 9526B** to provide time for the interested parties to come to agreement on the provisions of this subrule. The amendment adopted herein, which rescinds subrule 8.35(7) and adopts a new subrule in lieu thereof, is the result of those discussions and negotiations and has been agreed to by all parties to that process. Numerous comments were received and considered by the Board prior to the adoption of the prior amendment of 8.35(7), and those same comments were reviewed and considered with the adoption of this amendment.

The Board finds, pursuant to Iowa Code subsection 17A.5(2)“b”(2), that the normal effective date of this amendment, 35 days after publication, should be waived and the amendment should be made effective upon filing with the Administrative Rules Coordinator on August 11, 2011. This amendment confers a benefit to pharmacists, pharmacy owners, and patients by establishing requirements for closing a pharmacy, ensuring that all parties affected by a pharmacy closing are provided adequate advance notification of the closing and ensuring that pharmacy owners and pharmacists are aware of their responsibilities to patients and regulators when a pharmacy closes.

This amendment became effective August 11, 2011.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 155A.13.

The following amendment is adopted.

Rescind subrule 8.35(7) and adopt the following new subrule in lieu thereof:

8.35(7) Closing pharmacy. A closing pharmacy shall ensure that all patient and prescription records are transferred to another pharmacy that is held to the same standards of confidentiality as the closing pharmacy and that agrees to act as custodian of the records for the appropriate retention period for each record type as required by federal or state laws, rules, or regulations. A pharmacy shall not execute

a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy closing for delivery of the notifications to the pharmacist in charge, the board, the Drug Enforcement Administration (DEA), and pharmacy patients as required by this subrule. However, the provisions of this subrule regarding prior notifications to the board, the DEA, and patients shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

a. Pharmacist in charge notification. At least 40 days prior to the effective date of the sale of a pharmacy, the pharmacist in charge of the closing pharmacy, if that individual is not an owner of the closing pharmacy, shall be notified of the proposed sale. The owner of the closing pharmacy may direct the pharmacist in charge to maintain information regarding the pending closure of the pharmacy confidential until public notifications are required 30 days prior to the pharmacy closing. The pharmacist in charge of the closing pharmacy shall provide input and direction to the pharmacy owner regarding the responsibilities of the closing pharmacy, including the notifications, deadlines, and time lines established by this subrule. The pharmacist in charge of the closing pharmacy shall prepare patient notifications pursuant to paragraph 8.35(7) “d.” At least 30 days prior to the effective date of the sale of a pharmacy, the pharmacist in charge of the purchasing or receiving pharmacy, if that individual is not an owner of the pharmacy, shall be notified of the pending transaction.

b. Board and DEA notifications. At least 30 days prior to the closing of a pharmacy, including a closing by sale of a pharmacy, a written notice shall be sent to the board and to the Drug Enforcement Administration (DEA) notifying those agencies of the intent to discontinue business or to sell the pharmacy and including the anticipated date of closing. These prior notifications shall include the name, address, DEA registration number, Iowa pharmacy license number, and Iowa controlled substances Act (CSA) registration number of the closing pharmacy and of the pharmacy to which prescription drugs will be transferred. Notifications shall also include the name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which prescription files, patient profiles, and controlled substance receipt and disbursement records will be maintained.

c. Terms of sale or purchase. If the closing is due to the sale of the pharmacy, a copy of the sale or purchase agreement, not including information regarding the monetary terms of the transaction, shall be submitted to the board upon the request of the board. The agreement shall include a written assurance from the closing pharmacy to the purchasing pharmacy that the closing pharmacy has given or will be giving notice to its patients as required by this subrule.

d. Patient notification. At least 30 days prior to closing, a closing pharmacy shall make a reasonable effort to notify all patients who had a prescription filled by the closing pharmacy within the last 18 months that the pharmacy intends to close, including the anticipated closing date.

(1) Written notification shall identify the pharmacy that will be receiving the patient’s prescriptions and records. The notification shall advise patients that if they have any questions regarding their prescriptions and records that they may contact the closing pharmacy. If the closing pharmacy receives no contact from the patient within the 30-day notification period prior to the pharmacy closing, all patient information will be transferred to the receiving pharmacy. The notification shall also advise patients that after the date of closing patients may contact the pharmacy to which the prescriptions and records have been transferred.

(2) Written notification shall be delivered to each patient at the patient’s last address on file with the closing pharmacy by direct mail or personal delivery and also by public notice. Public notice refers to the display, in a location and manner clearly visible to patients, of signs in pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, or at pharmacy prescription counters. In addition, notice may be posted on the pharmacy’s Web site, displayed on a marquee or electronic sign, communicated via automated message on the pharmacy’s telephone system, or published in one or more local newspapers or area shopper publications.

e. Patient communication by receiving pharmacy. A pharmacy receiving the patient records of another pharmacy shall not contact the patients of the closing pharmacy until after the transfer of those patient records from the closing pharmacy to the receiving pharmacy and after the closure of the closing pharmacy.

f. Prescription drug inventory. A complete inventory of all prescription drugs being transferred shall be taken as of the close of business. The inventory shall serve as the ending inventory for the closing pharmacy as well as a record of additional or starting inventory for the pharmacy to which the drugs are transferred. A copy of the inventory shall be included in the records of each licensee.

(1) DEA Form 222 is required for transfer of Schedule II controlled substances.

(2) The inventory of controlled substances shall be completed pursuant to the requirements in 657—10.35(124,155A).

(3) The inventory of all noncontrolled prescription drugs may be estimated.

(4) The inventory shall include the name, strength, dosage form, and quantity of all prescription drugs transferred.

(5) Controlled substances requiring destruction or other disposal shall be transferred in the same manner as all other drugs. The new owner is responsible for the disposal of these substances as provided in rule 657—10.18(124).

g. Surrender of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing or selling pharmacy shall be returned to the board office within ten days of closing or sale. The DEA registration certificate and all unused DEA Forms 222 shall be returned to the DEA within ten days of closing. All authorizations to utilize the DEA's online controlled substances ordering system (CSOS) and all digital certificates issued for the purpose of ordering controlled substances for the closing pharmacy shall be canceled or revoked within ten days of closing.

h. Signs at closed pharmacy location. A location that no longer houses a licensed pharmacy shall not display any sign, placard, or other notification, visible to the public, which identifies the location as a pharmacy. A sign or other public notification that cannot feasibly be removed shall be covered so as to conceal the identification as a pharmacy. Nothing in this paragraph shall prohibit the display of a public notice to patients, as required in paragraph 8.35(7) "d," for a reasonable period not to exceed six months following the pharmacy closing.

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